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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,935	07/11/2003	Catherine Drogin	465/2	3966
27171	7590	02/22/2006	EXAMINER	
MILBANK, TWEED, HADLEY & MCCLOY 1 CHASE MANHATTAN PLAZA NEW YORK, NY 10005-1413			COMSTOCK, DAVID C	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/617,935

Applicant(s)

DROGIN ET AL.

Examiner

David Comstock

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 and 8-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 8-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In amended independent claims 1, 12, 17 and 18, the limitation "non-infant, youthful" referring to the patient does not find sufficient support in in the original disclosure which only sets forth that the device is for, as applicant stated in the remarks, "the empowerment of *the young patient...*" (Specification, page 4, lines 17-20 and Remarks, page 10, lines 18-19, emphasis added). "Young" is not necessarily tantamount to "non-infant and youthful." In fact, it is noted that in the declaration by the inventor, the direct mail campaign letter explicitly states that the device is for infants, "...FunDepressors' playful designs and vivid colors delight boys and girls from *infancy* through childhood." (emphasis added). This newly added negative limitation to overcome such references as Esker et al. was not set forth or apparently appreciated at the time of the original filing of the disclosure.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9 and 11-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Esker et al. (5,946,773).

Esker et al. disclose a flat stick 12 capable of being used as a tongue depressor. It is of a standard size for infants (~4 ½" x 3/8"), and even if not optimally, is also capable of being used on patients of all ages with an illuminated handle. The ends have a rounded profile (see Fig. 2). A decorative design is printed on the stick and any portion of the stick can be safely inserted into a mouth. The stick has a first side 16 and a second side 18 (see Figs. 1-6 and col. 1, lines 4-9). Various ornamental images formed of biocompatible inks appear on both sides 16, 18 of the device and may be multi-colored (id. and see col. 2, lines 25-37 and col. 4, lines 1-16 and 60-63). The images cover substantially all of both sides in various patterns and configurations. It is noted that an image on the first side can be the same as an image on the second side, e.g. a bunch of grapes (see Fig. 3). In addition, an image on the first side, e.g. a bunch of grapes, can be different from an image on the second side, e.g. an apple. The sides 16, 18 of the device can be contacted by a user's tongue. Any portion of the device, including a portion with an image, can be received within a user's mouth due to the

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biocompatibility of the ink forming the images and an additional biocompatible protective layer (see col. 2, lines 28-48). The device is made of plastic, i.e. styrene, and is protected with a layer of plastic (see col. 2, lines 38-51).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esker et al. (5,946,773).

Esker et al. disclose the claimed invention except for the device being formed from wood or cardboard. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the device from wood or cardboard, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 1-6 and 8-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (2004/0109932) in view of Esker et al. (5,946,773).

Chen et al. disclose a tongue depressor, which includes two sides and two tongue contact portions (see paragraphs 0002, 0003, 0063 and 0064). Tongue depressors are sterile. Chen does not disclose providing an ornamental image. Esker

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et al. disclose a similar device having decorative images formed from biocompatible inks on both sides of the device to make the device attractive and entertaining and to make the device more valuable to the user (see Figs. 1-6; col. 2, lines 25-37; and col. 4, lines 1-16 and 60-63). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the tongue depressor of Chen et al. with decorative images formed from biocompatible inks on both sides of the device, in view of Esker et al., in order to make the device attractive and entertaining and to make the device more valuable to the user. It is noted that providing different images on the two sides would have been an obvious matter of design choice, since applicant has not disclosed that providing the images in this way solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well without providing the images in this manner. Moreover, providing different images on each side is merely one of numerous configurations a person of ordinary skill in the art would find obvious. *In re Dailey and Eilers*, 149 USPQ 47 (1966). The sides of the device of the combination of Chen et al. and Esker et al. can be contacted by a user's tongue, and any portion of the device, including a portion with an image, can be received within a user's mouth due to the biocompatibility of the ink forming the images and an additional biocompatible protective layer (see col. 2, lines 38-48). It also would have been obvious to form this device from wood, plastic, cardboard, or any of numerous other known materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Moreover, it is noted that it would

have been obvious to provide the depressor, or any standard prior art tongue depressor, with decorative indicia, since the functional relationship between the decorative printed matter and the substrate, i.e. the tongue depressor, is merely that the tongue depressor supports the decorative printed matter. However, where the printed matter merely enhances or decorates a substrate, the functional relationship between the two is insufficient to distinguish the invention in terms of patentability. See *In re Ngai*, 367 F.3d 1336 (C.A.Fed. 2004) and *In re Gulack*, 703 F.2d 1381 (Fed. Cir. 1983).

### ***Response to Amendment***

The declaration under 37 CFR 1.132 filed 21 November 2005 is insufficient to overcome the outstanding rejections, over Esker et al. and/or Chen et al., set forth in the last Office action because: the arguments depend on new negative limitations in the claims that are unsupported in the original disclosure (see the rejection under 35 USC 112 above). The evidence also does not establish that the success of the invention was due only to technical or patentable merits as opposed to the amount of money or marketing skill of applicant. It is noted that applicant states that she has extensive --some 15 years--of marketing experience (see Applicant's Exhibit A, page 3, lines 5-6). In addition, it is simply unconvincing that it is somehow unexpected for a decoration to be pleasing to a child and yield positive benefits; it is axiomatic that children like bright colors and decorative items.

### ***Response to Arguments***

Applicant's arguments filed 21 November 2005 have been fully considered but they are not persuasive.

In response to applicant's argument pertaining to the intended use of the device with a self-illuminating tongue depressor handle attachment, it is noted that a recitation of the intended use of the claimed invention must result in a *structural* difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is *at least capable* of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). As noted in the rejection, the device is at least capable of being used in a self-illuminating tongue depressor handle attachment, and that it may not be optimal does not change this fact. Moreover, applicant has not established that there is not a self-illuminated handle attachment of a size suitable for an infant tongue depressor.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. Comstock  
20 February 2006



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SUPERVISORY PATENT EXAMINER